IN THE UNITED STATES DISTRICT COURT FOR THE
MIDDLE DISTRICT OF TENNESSEE
NASHVILLE DIVISION

RUTH SMITH, Individually and as Widow for the Use and Benefit of Herself and the Next Kin of Richard Smith, Deceased,	)	
Plaintiff,	)	Civil No. 3:05-0444
	)	Judge Aleta A. Trauger
v.	)	(Dist. Of MA No. 1:05-cv-11515PBS)
PFIZER, INC., *et al.*,	)	
Defendants.	)	

MEMORANDUM OF LAW IN SUPPORT OF DEFENDANTS' MOTION *IN LIMINE* TO EXCLUDE EVIDENCE OF POST-INCIDENT REGULATORY ACTIONS, LABELING, AND PATIENT INFORMATION GUIDES

Defendants Pfizer Inc and Warner-Lambert Company LLC (collectively, "Defendants" or "Pfizer") respectfully submit this memorandum of law in support of their motion *in limine*, pursuant to Federal Rules of Evidence 401, 402, 403, and 407, to exclude all evidence of and references to Food and Drug Administration ("FDA") regulatory actions related to Neurontin, including labeling, labeling changes, and patient information guides for Neurontin, that were issued after Mr. Smith's death in May 2004.

This evidence is irrelevant to the present action because it has no bearing on the issue of the adequacy of Neurontin's warnings at the time it was prescribed to and allegedly taken by Mr. Smith in 2004. Moreover, any marginal probative value of subsequent labeling and patient information guides is far outweighed by the likelihood that they would unfairly prejudice Defendants and mislead and confuse the jury. Additionally, this evidence is barred by Rule 407, which prohibits the introduction of such subsequent remedial measures for the purpose of demonstrating liability. Accordingly, all such evidence must be excluded.

ARGUMENT

I. NEURONTIN'S POST-INCIDENT LABELING AND PATIENT INFORMATION GUIDES ARE IRRELEVANT TO THIS ACTION

Plaintiff has included the FDA's April 2009 labeling for Neurontin and documents surrounding this revised label in her pretrial exhibit designations. The April 2009 labeling includes an additional warning about an increased risk of suicidal behavior and ideation based on the FDA's 2008 pooled analyses of data for eleven different antiepileptic drugs. (*See* Ex. A, April 2009 Neurontin Label, at 10.) Evidence about this current label and new warning, issued nearly five years after Mr. Smith's suicide in May 2004, is inadmissible because it is irrelevant to any of Plaintiff's remaining claims. *See, e.g.*, *United States v. Vasilakos,* 508 F.3d 401, 409 (6th Cir. 2007) ("'Evidence which is not relevant is not admissible.'" (quoting Fed. R. Evid. 402)). Plaintiff's claims concern, and challenge, only the adequacy of the warnings at the time Neurontin was prescribed to and allegedly taken by Mr. Smith (between March 2004 and May 2004).

The FDA's current labeling requirements for Neurontin are not probative of the adequacy of Neurontin's warnings at the time it was prescribed to and allegedly ingested by Mr. Smith. Indeed, it is axiomatic that one is not liable for failing to warn of alleged risks that it did not know, and could not have known, through the exercise of reasonable care. *Kibbler v. Richards Med. Co.*, No. 02A01-9110-CV-00214, 1992 WL 233027, at *2 (Tenn. Ct. App. Sept. 23, 1992) (citing *Browder v. Pettigrew*, 541 S.W.2d 402, 404 (Tenn. 1976)). Further, evidence of subsequent precautionary measures by a manufacturer "in no way supports an inference that the initial version of the product was defective." *Werner v. Upjohn Co.*, 628 F.2d 848, 857 (4th Cir. 1980).

In addition, evidence of post-2004 labeling and regulatory action does not bear on the issue of causation. As the MDL court has recognized, "the decision by the FDA to require warnings on a drug label, without more, does not suffice to establish causation" because "the FDA often uses a different standard than a court does to evaluate evidence of causation in a

products liability action." *In re Neurontin Mktg., Sales Practices, & Prods. Liab. Litig.*, 612 F. Supp. 2d 116, 136-37 (D. Mass. 2009). Indeed, the FDA may "err on the side of caution," *Rider v. Sandoz Pharms. Corp.*, 295 F.3d 1194, 1201 (11th Cir. 2002), and take action "upon a lesser showing of harm to the public than the . . . standard used to assess tort liability." *McClain v. Metabolife Int'l, Inc.*, 401 F.3d 1233, 1250 (11th Cir. 2005); *accord Glastetter v. Novartis Pharms. Corp.*, 252 F.3d 986, 991 (8th Cir. 2001) (observing that FDA conclusions are based on a "different standard than the causation standard at issue" in a personal injury action and recognizing that FDA regulatory "balancing" and warnings are "irrelevant in determining the threshold question [of causation]"). Accordingly, this evidence must be excluded as irrelevant.

II. NEURONTIN'S POST-INCIDENT LABELING AND PATIENT INFORMATION GUIDES WILL MISLEAD THE JURY AND UNFAIRLY PREJUDICE DEFENDANTS

Evidence of post-2004 regulatory actions, labeling, and patient information guides should also be excluded under Rule 403. Under Rule 403, if "the probative value of the evidence is substantially outweighed by its prejudicial character, the evidence is inadmissible." *United States v. Brady*, 595 F.2d 359, 361 (6th Cir. 1979); *see also Galarneau v. Merrill Lynch, Pierce, Fenner & Smith Inc.*, 504 F.3d 189, 205-06 (1st Cir. 2007) ("[E]ven where the evidence may shed light on the disputed issues, the district judge can find the 'untoward effects of the proffered evidence' to be so weighty that the evidence should be excluded." (citation omitted)). Rule 403 provides that the Court should evaluate whether jurors may give the evidence undue weight or use if for an improper purpose, and then determine whether the likelihood of such unfair prejudice would outweigh any probative value of the evidence. *See Cetlinski v. Brown*, 91 F. App'x 384, 393 (6th Cir. 2004) (holding that exclusion pursuant to Rule 403 is proper where "the admission of the [evidence] would . . . create[] a substantial danger of unfair prejudice and of confusion of issues and would . . . engender[] undue delay").

A chief purpose underlying the rule regarding subsequent remedial measures is to bar a class of evidence that is "inherently unreliable" and "very poor proof of negligence or

defectiveness." *Polec v. Northwest Airlines, Inc.* (*In re Air Crash Disaster*), 86 F.3d 498, 529-30 (6th Cir. 1996); *see also id. at* 530 n.21 (noting that evidence of subsequent remedial measures is excludable under Rule 403); *Bauman v. Volkswagenwerk Aktiengesellschaft*, 621 F.2d 230, 233 (6th Cir. 1980) (noting the extent of prejudice caused by evidence of remedial measures); *Bowling v. Scott County, Tenn.*, No. 3:04-CV-554, 2006 WL 2336333, at *6 (E.D. Tenn. Aug. 10, 2006) ("[A]t best, subsequent remedial measures are considered marginally probative of prior negligence." (quoting *Keller v. United States*, 38 F.3d 16, 31 (1st Cir. 1994))).

At the same time, evidence of subsequent remedial measures "distracts the jury from the relevant time frame for its inquiry, i.e., whether the product was defective *at the time of manufacture and sale.*" *Raymond v. Raymond Corp.*, 938 F.2d 1518, 1523 (1st Cir. 1991); *accord Grenada Steel Indus., Inc. v. Ala. Oxygen Co.*, 695 F.2d 883, 888 (5th Cir. 1983). The new labeling for Neurontin could not have been seen or relied upon by Mr. Smith's prescribers in connection with his prescriptions, and thus, any discussion of it would distract from the real issues in this case. Further, the jury might be misled to believe that Neurontin's subsequent labeling changes constitute an admission by Defendants that the prior label was inadequate. *See Mills v. Beech Aircraft Corp.*, 886 F.2d 758, 763 (5th Cir. 1989); *see also Lindsay v. Ortho Pharm. Corp.*, 637 F.2d 87, 94 (2d Cir. 1980) ("In view of the control over label terminology exercisable by the FDA, we question whether a change in language should be construed as a voluntary admission by the manufacturer." (citation omitted)).

Moreover, such evidence would cause unfair prejudice to Defendants, because it has an "'undue tendency to suggest a decision on an improper basis.'" *EEOC v. Allen Petroleum Co. of East Tenn., Inc.*, 893 F.3d 833 (6th Cir. 1996) (unpublished table decision), *text available at* 1996 WL 325249, at *3 (citation omitted). Specifically, the jury could be led to improperly infer medical causation on the basis of the later warning label. Indeed, in *Lindsay*, the Second Circuit concluded that the admission of subsequent labeling changes was "sufficiently damaging to the defendant that the case should be retried in its entirety, *including the medical issue of causal relation.*" *Lindsay*, 637 F.2d at 94 (emphasis added). Because these serious dangers of

prejudice and jury confusion substantially outweigh any marginal probative value of post-2004 regulatory action or labeling, such evidence must be excluded.

III. NEURONTIN'S POST-INCIDENT LABELING AND PATIENT INFORMATION GUIDES ARE INADMISSIBLE AS SUBSEQUENT REMEDIAL MEASURES

Neurontin's 2009 warning label and patient information guides issued after Mr. Smith's death are also inadmissible to show liability under Rule 407, which governs evidence of subsequent remedial measures. The Rule provides:

> When, after an injury or harm allegedly caused by an event, measures are taken that, if taken previously, would have made the injury or harm less likely to occur, evidence of the subsequent measures is not admissible to prove negligence . . . or a need for a warning or instruction.

Fed. R. Evid. 407; *see also Bryan v. Emerson Elec. Co.*, 856 F.2d 192 (6th Cir. 1988) (unpublished table decision), text available at 1988 WL 90910, at *2 (stating that courts should "construe . . . exceptions [to the prohibition in Rule 702] narrowly in a careful attempt to preserve the essence of the Rule's proscription against admission"). Federal courts of appeals have repeatedly held that Rule 407 precludes admission of evidence of subsequent changes to a prescription drug's labeling to prove that a prior warning was inadequate. *See, e.g.*, *Stahl v. Novartis Pharms. Corp.*, 283 F.3d 254, 270 n.10 (5th Cir. 2002); *Lindsay*, 637 F.2d at 94; *Werner*, 628 F.2d at 854; *see also Gray v. Hoffman-La Roche, Inc.*, 82 F. App'x 639, 646 (10th Cir. 2003) (finding that a post-incident patient informed-consent form in pharmaceutical products liability suit "fit[] squarely within the category of evidence Rule 407 bars"). For instance, in *Stahl*, the plaintiff alleged that he had contracted hepatitis from the defendant's medication, and he proffered a package insert that had been revised after his injury to include further warning about such liver conditions. *Stahl*, 283 F.3d at 259-60, 270 n.10. The Fifth Circuit held that "[s]uch evidence . . . cannot be considered in evaluating whether the [prior] warning was adequate." *Id.* at 270 n.10; *accord Gerber v. Hoffman-La Roche Inc.*, 392 F. Supp. 2d 907, 919 (S.D. Tex. 2005). The same result is required here.

Plaintiff cannot obtain admission of this evidence for any alternate purpose permitted by Rule 407. As established above, post-incident labeling changes are not relevant to show causation. Nor may Plaintiff offer this evidence to demonstrate feasibility of a different warning, as feasibility is not disputed here. *See* Fed. R. Evid. 407 ("This rule does not require the exclusion of evidence of subsequent measures when offered for another purpose, such as proving . . . feasibility of precautionary measures, *if controverted* . . . ." (emphasis added)); *Cameron v. Otto Back Orthopedic Indus., Inc.*, 43 F.3d 14, 17 (1st Cir. 1994) (noting that subsequent remedial measures are inadmissible under Rule 407 where feasibility was not in dispute).[1]

CONCLUSION

For the foregoing reasons, this Court should exclude all references to and evidence related to the FDA's regulatory actions, labeling, and patient information guides for Neurontin after Mr. Smith's death in May 2004.

[1] Plaintiff may argue that Rule 407 poses no bar to evidence of post-incident label changes because the label-change decision was made by the FDA, not by Defendants. This argument was squarely rejected by the Fourth Circuit in *Werner*, on the basis that the FDA "also relies on voluntary compliance and compromise in determining the content of warnings and advertising for prescription drugs." *Werner*, 628 F.2d at 859. Moreover, even if such evidence is not inadmissible under Rule 407, it should nevertheless "be excluded under Fed. R. Evid. 403," where, as here, "its probative value is outweighed by the unfair prejudice that could result." *Raymond*, 938 F.2d at 1524; *see also id.* at 1523 (affirming exclusion of subsequent remedial measures and citing Rule 407's purpose "to avoid unfairly prejudicing the defendant").

Dated: April 16, 2010

Respectfully submitted,

SKADDEN, ARPS, SLATE,
MEAGHER & FLOM LLP

By: /s/ Mark S. Cheffo
Mark S. Cheffo

Four Times Square
New York, NY 10036
Tel: (212) 735-3000

-and-

NEAL & HARWELL, PLC

By: /s/ Gerald D. Neenan
Aubrey B. Harwell, Jr., No. 002559
W. David Bridgers, No. 016603
Gerald D. Neenan, No. 006710

2000 One Nashville Place
150 Fourth Avenue, North
Nashville, TN 37219
(615) 244-1713
(615) 726-0573 (fax)

Attorneys for Defendants Pfizer Inc and Warner-Lambert Company LLC

CERTIFICATE OF SERVICE

I hereby certify that on this the 16th day of April 2010, I electronically filed the foregoing document with the Clerk of the Court, United States District Court for the Middle District of Tennessee, using the CM/ECF system. True and correct copies of the foregoing documents are being served via the Court's CM/ECF system on the following:

Andrew G. Finkelstein, Esq.
Kenneth B. Fromson, Esq.
Finkelstein & Partners, LLP
436 Robinson Avenue
Newburg, NY 12550

Charles F. Barrett, Esq.
Barrett & Associates, P.A.
6718 Highway 100, Suite 210
Nashville, TN 37205

Dara G. Hegar, Esq.
Ken S. Soh, Esq.
Maura Kolb, Esq.
Robert Leone, Esq.
W. Mark Lanier, Esq.
Lanier Law Firm
6810 FM 1960 West
Houston, TX 77069

/s/ Gerald D. Neenan